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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FORD, ALLISON M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 03/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/714,569	ALTMEYER ET AL.	
	Examiner	Art Unit	
	Allison M Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/3/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *4-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 8-15* is/are rejected.

7)☒ Claim(s) *2,8 and 15* is/are objected to.

8)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Several elections of species were required in the current application. In the reply filed 1/3/05 applicant made following elections:

Election of claim 2, addition of disulfide bond cleaving reducing or oxidizing reagents as the species of chemical or bio-catalytic conversion.

Election of thiols, from claim 3, as the species of disulfide bond cleaving reducing or oxidizing agent.

Election of matrix assisted laser desorption ionization (MALDI), from claim 9, as the species of mass-spectrometric ionization method.

Election of liquid chromatography, from claim 11, as the species of liquid chromatography.

Claim 4 should be dependent on claim 1; claim 6 should be dependent on claim 5. Thus, upon the election of claim 2 as the species of chemical or bio-catalytic conversion, claims 4, 5, 6 and 7 become directed to non-elected species and are therefore withdrawn from consideration during initial prosecution.

These elections were made without traverse.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 371, which papers have been placed of record in the file. Additionally, acknowledgment is made of applicant's claim for foreign priority based on PCT/DE02/01737 filed on 5/15/02, which further claims priority to German national application DE 101 23 711 filed on 5/15/01. It is noted however, that applicant has not filed a certified copy of the international application or the German application as required by 35 USC 119(b).

Specification

On page 1 applicant provides the cross-reference information to related applications; however, applicant claims priority to German Patent application 101 22 711.1, filed May 15, 2001. The oath states that priority is claimed to German Patent application 101 23 711; though neither of these documents were received with the application, it appears 101 23 711 is the appropriate document. Appropriate correction is required.

Additionally, the title is spelled incorrectly; it should read, "METHOD FOR QUALITATIVE AND/OR QUANTITATIVE DETERMINATION OF GENUS, SPECIES, RACE AND/OR GEOGRAPHICAL ORIGIN OF BIOLOGICAL MATERIAL." Appropriate correction is required.

Claim Objections

Claim 2 is objected to because, while it is not so unclear as to render the claim indefinite, its intention is obscured. It appears the claim intends the addition of the disulfide bond cleaving reducing or oxidizing agent to be the specific chemical or bio-catalytic agent that converts the scales, hair, feathers, down and/or horn or parts thereof into a pool of cleavage peptides or derivatives of these cleavage peptides in step a) of claim 1. This would be clearer if written, "...wherein in step a) disulfide bond cleaving reducing or oxidizing agents are added to act as the agent for the specific chemical or bio-catalytic conversion."

Claim 8 is objected to because it recites the limitation "the detection step for fragments so generated" in the first line of the claim. It appears applicant is referring to step (b) (of claim 1) wherein cleavage-peptides or derivatives of the cleavage peptides are detected; it would be clearer if applicant claimed, "The method according to claim 2, wherein the detection step (b) of the cleavage-peptides or derivatives of the cleavage peptides includes a mass-spectrometric ionization method." Again, the language is not so unclear as to render the claim indefinite, but is

deemed confusing as written.

Claim 15 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 8-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's claim 1 is directed to a method for the qualitative and for quantitative determination of genus, species, breed and/or geographic origin of biological materials on the basis of scales, hair, feathers, down and/or horn, comprising the steps: a) converting the scales, hair, feathers, down and/or horn or parts of them by means of specific chemical or bio-catalytic conversion into a pool of cleavage peptides or derivatives of these cleavage peptides; b) detecting the cleavage peptides or derivatives of these cleavage peptides individually or in groups by means of mass spectrometry; and c) comparing individual analysis signals or groups of signals, by comparing the signals with those of reference samples for determination of genus, species, breed, and/or geographical origin of the material. However the specification teaches the fibril structures

from feathers, down, scales, hair or horn must first be directly cleaved by specific enzymes to a pool or cleavage peptides (See Spec, Pg. 6, paragraph 0014). This cleavage is not a total hydrolysis or an unspecific hydrolysis of keratin structure (See Spec, Pg. 7, paragraph 0016); rather it is a specific enzymatic cleavage of fibril structure with defined cleavage sites (See Spec, Pg. 7, paragraph 0017). This specific enzymatic cleavage differentiates the current method from those taught in the prior art.

However, applicant fails to provide sufficient written description of the specific enzyme that performs the specific enzymatic cleavage. One of ordinary skill in the art knows that different enzymes cleave proteins at specific amino acid junctions; however, applicant has not sufficiently described the specific enzyme used, or the site of cleavage. Therefore, the specific enzymatic cleavage that is crucial for differentiating the current method, has not been described, and thus cannot be treated as unique. Claims 2-3 and 8-15 have the limitations of claim 1 and thus are rejected on the same basis.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 8-15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

Applicant's claim 1 is directed to a method for the qualitative and for quantitative determination of genus, species, breed and/or geographic origin of biological materials on the basis of scales, hair, feathers, down and/or horn, comprising the steps: a) converting the scales, hair, feathers, down and/or horn or parts of them by means of specific chemical or bio-catalytic conversion into a pool of cleavage peptides or derivatives of these cleavage peptides; b) detecting

the cleavage peptides or derivatives of these cleavage peptides individually or in groups by means of mass spectrometry; and c) comparing individual analysis signals or groups of signals, by comparing the signals with those of reference samples for determination of genus, species, breed, and/or geographical origin of the material. However, the specification teaches that the method requires the fibril structures from feathers, down, scaled, hair or horn to be directly cleaved by specific enzymes to a pool or cleavage peptides (See Spec, Pg. 6, paragraph 0014). Exemplary enzymes include trypsin, chymotrypsin, endoproteinase Glu- C (V8- Protease), endoproteinase Lys-C, endoproteinase Arg-C, endoproteinase Asp-N, thrombin, papain, pepsin, plasmin or mixtures of such enzymes. Therefore the method omits the essential step of addition of specific enzymes for the selective cleavage of the keratin structures. Claims 2-3 and 8-15 have the limitations of claim 1 and thus are rejected on the same basis.

Claims 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's claim 10 is directed to the method of claim 2, wherein the generated fragments are separated and detected by liquid chromatography. First, the limitation, "the generated fragments" is recited in the first line of the claim, there is insufficient antecedent basis for this limitation. Claim 1 recites cleavage peptides or derivatives of the cleavage peptides. It appears "fragments" is intended to refer back to the cleavage peptides, however the same terminology must be used throughout the claims. Second, claim 10 does not seem to correlate properly with the steps of claim 2. Claim 2 is directed to the method of claim 1, wherein the detection of the cleavage peptides or derivatives thereof are detected by means of mass spectrometry; claim 10 requires the cleavage peptides to be detected by means of liquid chromatography. It is not clear if the liquid chromatography is to be performed in lieu of the

mass spectrometry, which would constitute a distinct method, or if the liquid chromatography is to be performed in addition to the mass spectrometry, in which case it is not clear how or when the liquid chromatography is to be performed (See Spec, Pg. 9, paragraph 0023). Third, the step of chromatographic separations seems to be repugnant to the teachings in the specification, which specifically states the current method requires no subsequent separation, enrichment or isolation of single isolated proteins (See Spec Pg 7, paragraph 0015). Therefore it is not clear why a separation step is claimed. Claim 11 has the limitation of claim 10 and thus is rejected on the same basis.

Applicant's claim 12 is directed to the method of claim 2, wherein the generated fragments are separated and detected by means of capillary electrophoretic methods. First, the limitation, "the generated fragments" is recited in the first line of the claim, there is insufficient antecedent basis for this limitation. Claim 1 recites cleavage peptides or derivatives of the cleavage peptides. It appears "fragments" is intended to refer back to the cleavage peptides, however the same terminology must be used throughout the claims. Second, claim 12 does not seem to correlate properly with the steps of claim 2. Claim 2 is directed to the method of claim 1, wherein the detection of the cleavage peptides or derivatives thereof are detected by means of mass spectrometry; claim 11 requires the cleavage peptides to be separated and detected by means of capillary electrophoretic methods. It is not clear what capillary electrophoretic method is to be performed, or if the capillary electrophoretic method is to be performed in lieu of the mass spectrometry, which would constitute a distinct method, or if the capillary electrophoretic method is to be performed in addition to the mass spectrometry, in which case it is not clear how or when the capillary electrophoretic method is to be performed (See Spec, Pg. 9, paragraph 0023). Third, the step of capillary electrophoretic separation seems to be repugnant to the teachings in the specification, which specifically states the current method requires no subsequent separation, enrichment or isolation of single isolated proteins (See Spec Pg 7, paragraph 0015).

Therefore it is not clear why a separation step is claimed.

Applicant's claim 13 is directed to the method of claim 2, further comprising the step of processing samples by means of a robot and/or by the use of mixing-heating and cooling devices. It is not clear what the step of processing achieves, i.e. what is being processed, or at what point it is performed in the method of claim 2. Claim 14 has the limitations of claim 13 and thus is rejected on the same basis.

Applicant's claim 14 is further rejected as being indefinite. Claim 14 is directed to the method of claim 13, wherein the samples are transferred from one or more microtiter plates in one or more analytical devices. It is not clear what the sample consist of, or what types of analytical devices are being used. Claim 2 requires the pools of cleavage peptides to be detected by means of mass spectrometry, therefore it appears the samples comprise the cleavage peptides, and the analytical device is the mass spectrometer.

Claim 15 provides for the use of the method of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. It appears the steps to use of the method of claim 1 to identify the origin of biological materials, as claimed in claim 15, is already recited in claim 1, step c): comparing individual analysis signals or groups of signals, by comparing the signals with those of reference samples for determination of genus, species, breed and/or geographical origin of the material. Thus claim 15 would be a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 8-9, 13-14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krishnamurthy et al (US Patent 6,177,266), in view of Baumgartner (US Patent 5,466,579) and Smith et al (Methods in Enzymology, 1990).

Applicant's claim 1 is directed to a method for the qualitative and for quantitative determination of genus, species, breed and/or geographic origin of biological materials on the basis of scales, hair, feathers, down and/or horn, comprising the steps: a) converting the scales, hair, feathers, down and/or horn or parts of them by means of specific chemical or bio-catalytic conversion into a pool of cleavage peptides or derivatives of these cleavage peptides; b) detecting the cleavage peptides or derivatives of these cleavage peptides individually or in groups by means of mass spectrometry; and c) comparing individual analysis signals or groups of signals, by comparing the signals with those of reference samples for determination of genus, species, breed, and/or geographical origin of the material. Claim 2 requires in step a) the specific chemical or biocatalytic conversion to be achieved by addition of a disulfide bond cleaving reducing or oxidizing agent. Claim 3 requires the disulfide bond cleaving reducing or oxidizing agent to be a thiol. Claim 8 requires the detection step b) to include a mass-spectrometric ionization method. Claim 9 requires the mass- spectrometric ionization method to be matrix assisted laser desorption mass spectrometry (MALDI). Claim 13 requires the further step of processing samples by means of a robot and/or by the use of mixing-heating and cooling devices. Claim 14 requires the

samples to be transferred by one or multiple robots from one or more microtiter plates in one or more analytical devices.

Krishnamurthy et al teach a method for the chemotaxonomic classification of bacteria based on the presence and identification of genus and species-specific biomarkers present in the cellular protein content (See col. 1, ln 53-67). The method comprises lysing bacteria cells of unknown origin using beta-mercaptoethanol and DNAase to obtain bacteria protein extract (which applicant calls conversion by means of specific chemical or biocatalytic conversion into a pool of cleavage peptides or derivatives); detecting the cleavage peptides in the cellular extract by means of MALDI-TOF mass spectrometry; and then comparing the mass spectra to those of reference samples to determine species of bacteria (See col. 3, ln 22- col. 5, ln 55) (Claims 1-3 and 8-9).

Though Krishnamurthy et al use bacteria protein extracts, and not peptides extracted from scales, hair, feathers, down and/or horn, it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Krishnamurthy et al, comprising obtaining cellular protein extracts (which applicant calls cleavage peptides), obtaining mass spectra by MALD-TOF mass spectrometry (which applicant calls detecting the cleavage peptides); and comparing the mass spectra (analysis signals) to those of reference samples for determination of genus and species, with protein extracts or cleavage peptides from any cellular source, including scales, hair, feathers, down and/or horn. One of ordinary skill in the art would have been motivated to determine the origin of biological materials such as scales, hair, feathers, down and/or horn in order to identify and classify unknown samples. For example, Krishnamurthy et al was motivated to determine the origin, genus and species of bacteria samples in order to diagnose diseases and predict on-coming public health hazards, as well as to distinguish between related species, wherein phenotypic differences are not definitive (See col. 1, ln 24-32). Though the animals that would provide the scales, hair, feathers, down and/or horn are

less likely to be the cause of on-coming health hazards or biological warfare, determining the identity and origin of an unknown source would allow conservation biologists to monitor animal migrations and presence in field studies. For example, using protein extracts from scales, hair, feathers, down and/or horn in the method of Krishnamurthy et al collected in the field would enable the skilled artisan to unambiguously decipher between species that are phenotypically indistinct or difficult to observe, thus providing accurate identification of the species present in that particular area of study.

One would have expected success performing the analysis method of Krishnamurthy et al on proteins or peptide fragments from any origin, including from scales, hair, feathers, down and/or horn because MALDI-TOF mass spectrometry is especially suited to analysis of crude protein extracts, and is capable of deterring the mass of proteins of between 1 and 40 kDa with accuracy of ± 0.1% (See col. 2, ln 19-59) and methods of extracting proteins and hydrolysates from keratin containing material (such as scales, hair, feathers, down and/or horn) is well known in the art. For example, Baumgartner teach a method for hydrolyzing keratinized structures comprising dissolving a sample of keratinized structure in a solution containing dithiothreitol (DTT) or dithrioerythritol (DTE) and an enzyme suitable for the dissolution of keratinized structure, such as papain, to form a keratin digest solution (which applicant calls a pool of cleavage peptides) (See col. 4, ln 58-col. 5, ln 12). Smith et al also teach additional enzymes, such as trypsin, chymotrypsin, and pepsin that can also be used for the specific cleavage of peptides (See Smith et al, Pg. 378-379). Digestion of keratinized structures, such as hair, by treatment with a thiol, such DTT or DTE, and specific cleavage with a hydrolyzing enzyme, such as papain, or the alternative enzymes taught by Smith et al, is the same process as taught in the present application (See pg. 9, paragraph 0023); thus the keratin digest solution obtained by the method of Baumgartner is one and the same as the pool of cleavage peptides formed in the present application. Therefore one of ordinary skill in the art would have expected success

converting keratinized structures such as scales, hair, feathers, down and/or horn into a pool of cleavage peptides by the method of Baumgartner, and would have expected success using these peptides in the analysis method of Krishnamurthy et al because MALDI-TOF mass spectroscopy is well suited for protein analysis, as described above (Claims 1-3, 8-9 and 15).

Additionally, though neither Krishnamurthy et al nor Baumgartner et al teach a step of processing the samples by means of a robot and/or by the use of mixing heating and cooling devices or transferring samples from one or more microtiter plates in one or more analytical devices, it would have been obvious to one of ordinary skill in the art at the time the invention was made to automate the MALDI-TOF mass spectrometry method of Krishnamurthy et al, using peptides obtained by the method of Baumgartner, so that samples were processed and transferred by means of a robot in the mass spectrometry system. Automated robotic systems that are capable of sequentially heating, cooling, mixing, and/or transferring samples are well known in the art. For example Douchy et al teach an automated mass spectrometry system that is capable of robotically processing and transferring precise quantities of samples from a container to its associated support, which in the case of a mass spectrometer would be the auto sampler pins (See Krishnamurthy et al, col. 4, ln 33-37) (which applicant calls one or more microtiter plates) (See Douchy et al, col. 1, ln 8-34 & col. 4, ln 10-36) (Claims 13-14). One of ordinary skill in the art would be motivated to use an automated system to reduce manual labor required to run the machine and to increase accuracy and reproducibility of the results, due to the precise nature of robotics (See, e.g. Douchy et al, col, 4, ln 27-36). One would have expected success because the automated machine of Douchy et al is designed specifically for mass spectrometry usage.

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Baumgartner (US Patent 5,466,579), in view of Stone et al (Methods in Enzymology, 1990).

Applicant's claims 10 and 11 are directed to a method for the qualitative determination of genus, species, breed and/or geographical origin of biological materials on the basis of scales, hair, feathers, down and/or horn comprising a) converting the scales, hair, feathers, down and/or horn or parts thereof into a pool of cleavage peptides or derivatives of cleavage peptides by addition of disulfide bond cleaving reducing or oxidizing reagents; separating and detecting the cleavage peptides by liquid chromatography; and comparing the analysis with those of reference samples for determination of genus, species, breed and/or geographical origin.

Baumgartner teach a method for hydrolyzing keratinized structures comprising dissolving a sample of keratinized structure in a solution containing dithiothreitol (DTT) or dithrioerythritol (DTE) and an enzyme suitable for the dissolution of keratinized structure, such as papain, to form a keratin digest solution (which applicant calls a pool of cleavage peptides) (See col. 4, ln 58-col. 5, ln 12). Dithiothreitol and dithrioerythritol reduce disulfide bonds. Scales, hair, feathers, down and/or horn are all well known examples of keratinized structures. Digestion of keratinized structures, such as hair, by treatment with a thiol, such DTT or DTE, and specific cleavage with a hydrolyzing enzyme, such as papain, or the alternative enzymes taught by Smith et al, is the same process as taught in the present application (See pg. 9, paragraph 0023); thus the keratin digest solution obtained by the method of Baumgartner is one and the same as the pool of cleavage peptides formed in the present application.

Though Baumgartner does not teach separating the cleaved peptides by liquid chromatography means it would have been obvious to one of ordinary skill in the art at the time the invention was made to separate and detect different, defining proteins in the cleavage peptide pool by liquid chromatography means because it is a commonly practiced method in the art for separating and detecting peptides. For example, Stone et al teach reversed-phase high performance liquid chromatography (HPLC) is the current method of choice for detecting and

separating mixtures of peptides derived from enzymatic and chemical cleavage of proteins, just as was performed by Baumgartner. Stone et al further teach HPLC is ideal for confirming the identity of proteins in a mixture, therefore one of ordinary skill in the art could use HPLC to compare elutes and elution rates to those of known peptides to determine the origin of biological materials (See Stone et al, Pg. 389) (Claims 10 and 11). One of ordinary skill in the art would have been motivated to determine the origin of biological materials such as scales, hair, feathers, down and/or horn in order to identify and classify unknown samples. Determining the identity and origin of an unknown source would allow conservation biologists to monitor animal migrations and presence in field studies. For example, using cleavage peptides from scales, hair, feathers, down and/or horn obtained by the method of Baumgartner collected in the field would enable the skilled artisan to unambiguously decipher between species that are phenotypically indistinct or difficult to observe, thus providing accurate identification of the species present in that particular area of study. One would have been motivated to separate and detect the different cleavage peptides by liquid chromatography means, such as by HPLC, because Stone et al teach that HPLC is the current method of choice for fractioning complex mixtures of peptides derived from the enzymatic and chemical cleavage of proteins (See Stone et al, pg. 389). One would have expected success because Baumgartner teaches successfully degrading keratinized structures such as hair using enzymes and disulfide bond cleaving agents, and Stone et al teach HPLC is particularly suited for separating peptides and confirming the identity of proteins (See Stone et al, pg, 389). Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner (US Patent 5,466,579), in view of Sanchez et al (Methods in Enzymology, 1990).

Applicant's claim 12 is directed to a method for the qualitative determination of genus,

species, breed and/or geographical origin of biological materials on the basis of scales, hair, feathers, down and/or horn comprising a) converting the scales, hair, feathers, down and/or horn or parts thereof into a pool of cleavage peptides or derivatives of cleavage peptides by addition of disulfide bond cleaving reducing or oxidizing reagents; separating and detecting the cleavage peptides by capillary electrophoresis; and comparing the analysis with those of reference samples for determination of genus, species, breed and/or geographical origin.

Baumgartner teach a method for hydrolyzing keratinized structures comprising dissolving a sample of keratinized structure in a solution containing dithiothreitol (DTT) or dithrioerythritol (DTE) and an enzyme suitable for the dissolution of keratinized structure, such as papain, to form a keratin digest solution (which applicant calls a pool of cleavage peptides) (See col. 4, ln 58-col. 5, ln 12). Dithiothreitol and dithrioerythritol reduce disulfide bonds. Scales, hair, feathers, down and/or horn are all well known examples of keratinized structures. Digestion of keratinized structures, such as hair, by treatment with a thiol, such DTT or DTE, and specific cleavage with a hydrolyzing enzyme, such as papain, or the alternative enzymes taught by Smith et al, is the same process as taught in the present application (See pg. 9, paragraph 0023); thus the keratin digest solution obtained by the method of Baumgartner is one and the same as the pool of cleavage peptides formed in the present application.

Though Baumgartner does not teach separating the cleaved peptides by capillary electrophoretic means it would have been obvious to one of ordinary skill in the art at the time the invention was made to separate and detect different, defining proteins in the cleavage peptide pool by capillary electrophoretic means because it is a commonly practiced method in the art for separating and detecting peptides (Claim 12). For example, Sanchez et al teach capillary electrophoresis is used to separate and detect large molecules such as proteins, as it is sensitive to the size, shape and charge of a peptide (See Pg. 469 and 478). One of ordinary skill in the art would have been motivated to determine the origin of biological materials such as scales, hair,

feathers, down and/or horn in order to identify and classify unknown samples. Determining the identity and origin of an unknown source would allow conservation biologists to monitor animal migrations and presence in field studies. For example, using cleavage peptides from scales, hair, feathers, down and/or horn obtained by the method of Baumgartner collected in the field would enable the skilled artisan to unambiguously decipher between species that are phenotypically indistinct or difficult to observe, thus providing accurate identification of the species present in that particular area of study. One would have been motivated to separate and detect the different cleavage peptides by capillary electrophoresis, because Sanchez et al teach that capillary electrophoresis is extremely sensitive to changes in charge, size and shapes of peptides, and can be used in combination with other analysis means, including HPLC and mass spectrometry (See pg. 478). One would have expected success because Baumgartner teaches successfully degrading keratinized structures such as hair using enzymes and disulfide bond cleaving agents, and Sanchez et al teach capillary electrophoresis is suited for separating peptides (See pg. 469 and 478). Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M Ford whose telephone number is 571-272-2936. The examiner can normally be reached on M-F 7:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
Art Unit 1651

LEON B. LANKFORD, JR.
PRIMARY EXAMINER